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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,364	12/05/2003	Raymond W. Sze	UNIV0162	8253

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EXAMINER

UTAMA, ROBERT J

ART UNIT	PAPER NUMBER
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3714

MAIL DATE	DELIVERY MODE
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08/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,364

Applicant(s)

SZE ET AL.

Examiner

Robert J. Utama

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-13,18-27,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,18-27,52 and 53 is/are rejected.
- 7) ☒ Claim(s) 14-17 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

1. In response to the applicant's amendment filed on: 06/08/2007. The current status of claim are as follows: Claim 1, 2, 4-27 and 52-53 are still pending. Claim 3 and 28-51 has been cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claim 1-2, 4-13, 18-27 and 52-53 rejected under 35 U.S.C. 103(a) as being unpatentable over Gain et al US 4,708,836 and further in view of NPL#1**

Claim 1 and 21: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material -epoxy resin- and the second material - oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The

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sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

Claim 2: Gain provides a teaching for a medical simulator having a second material that fills opening in the first material (see col. 12:44-56). However, Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

Claim 4 and 23: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material.

Claim 5 and 22: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

Claim 6: Gain provides a teaching where the model includes a scalp portion which include a scalp portion (see Gain FIG 15) and the scalp portion of the model is covered in layer of the

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second material, the second material covering at least a portion of the first material (see Gain col. 12:44-56). The limitation of "to prevent the simulated patent sutures from being identified tactilely" is being treated as an intended use limitation and currently not given patentable weight.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

Claim 7-9: The examiner contends that the reference of Gain and NPL #1 fails to show an ultrasound simulator with a patent suture that is filled with a mixture of starch and glue (**claim 7**). Similarly, the reference does not show the glue in the mixture to be a casein-based glue (**claim 8**) or a synthetic resin-based glue (**claim 9**). Instead, the combination of the Gain and NPL#1 reference used a mixture of oil and silicon (see col. col. 11:45-57).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model the sutures using a mixture of oil and silicon.or starch and glue mixtures. Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, the echogenicity of both materials are less than then solid portion of the skull. Therefore, it would have been prima facie obvious to modify Gain and NPL #1 to obtain the invention as specified in claim 7-9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Gain and NPL#1.

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Claim 10 and 11: Gain fails to provide a teaching of having a simulated patent skull sutures. The infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagittal and lambdoid sutures. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasound device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

Claim 12: Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures (see Gain FIG. 2).

Claim 13: Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures made from a first material (see Gain col. 5:43-67 artificial cranium).

Claim 18 and 19: Gain provides a teaching of an opaque layer configured to cover each of the simulated skull sutures and the scalp areas (see col. 12:44-56). The limitation of "so that a trainee cannot readily visually determine whether a specific skull sutures is patent or skull by inspecting the model" is being treated as an intended use limitation and currently not given patentable weight.

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Claim 20: Gain provides in teaching where the head is utilized for the substantially life size model of a human head (see col. 2:7-14).

Claim 26: Gain fails to provide a teaching of having a simulated patent skull sutures.

However, the infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagital and lambdoid sutures. The reference also shows that the sagital and metopic sutures are formed in a way that the opposites walls of the opening would meet in an end-to-end fashion. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasounic device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 26 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

Claim 27: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The

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difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant. While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark

Claim 52: Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain et al is silent on the limitation of “the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model.” The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

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Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

Claim 53: Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The examiner takes the position that the difference in density of the first material -epoxy resin- and the second material -oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

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Allowable Subject Matter

4. Claim 14-17 and 25 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments with respect to claim 1-2, 4-27 and 52-53 have been considered but are moot in view of the new ground(s) of rejection.

6. With respect applicant's argument on claim 4 and 15, applicant's argument and amendment are sufficient. Previous rejection on these claims have been withdrawn.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

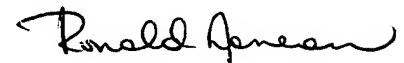
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert J. Utama whose telephone number is (571) 272-1676. The examiner can normally be reached on M-F 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezutto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RU



**RONALD LANEAU
PRIMARY EXAMINER
ART UNIT 3714**

8/18/07